Summary of Stakeholder Meeting to Explore Laboratory Biorisk Certification
26 February 2010
Brussels, Belgium

Following "CEN Workshop 55 - Guidance Document for CWA 15793:2008 Laboratory Biorisk Management Standard,[1]" over 40 individuals from 14 countries,[2] the European Commission, and OIE met to discuss whether there was interest in pursuing an international certification scheme for laboratory biorisk management systems (e.g. CWA 15793[3]) and possible next steps. Many different stakeholders were represented including laboratories (users) from developed and developing countries, professional biosafety associations, conformity assessment bodies, a national standards organization, government regulators and other interested government and non-governmental organizations.

Participants heard updates on the status and next steps of CWA 15793, perspectives and initiatives on laboratory certification and accreditation from members of the biorisk community, a conformity assessment body, and a national standards organization (the full agenda, brief summaries of the formal presentations, and speaker slides are attached). The meeting succeeded in its primary objective of sensitizing participants to important issues that must be addressed if a successful certification or accreditation scheme is to be developed.

Consensus Conclusions
The group agreed that:

- The development of a certification scheme for laboratory biorisk management should be pursued using CWA 15793 as the technical basis for that scheme.
- Although the details are still unclear regarding how a certification scheme would be run (who owns the scheme, how is it funded, etc), there was a feeling that the timing was right to develop a scheme that could provide international trust and recognition.
- A certification scheme should be developed with flexibility for national and local situations and to facilitate different uses, such as those users wanting to self-certify as well as users seeking third-party certification.
- As an international initiative, definitions for certification, accreditation, and other key terms should be drawn from internationally-accepted sources, such as ISO 17000.
- This group had the appropriate expertise to develop such a scheme but the group also acknowledged that additional stakeholders should be invited to participate.[4]

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[1] http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Pages/CWA15793-guide.aspx

[2] Australia, Belgium, Canada, Denmark, Egypt, Germany, Mexico, Netherlands, Norway, Pakistan, Singapore, Spain, Switzerland, and the United States

[3] ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf

[4] Suggestions for other stakeholders should be sent to Jennifer Gaudioso at jmgaudi@sandia.gov.

Key issues discussed

Potential impacts to the user community

The issues require careful attention to ensure that the user community is not unduly burdened. Multiple national and local schemes would be very difficult for multinational pharmaceutical and biotechnology companies.

There was significant discussion of the costs to a facility to pursue certification if a scheme is developed and that cost will be a significant variable in implementation. One participant gave an example of implementing a management system at an institution, describing the initial pain and seemingly high costs but that implementing the management system and being certified to it did deliver real value to the facility. Another participant highlighted that scientists may not know what is best from a laboratory management perspective; the value delivered and wide acceptance of ISO 17025 despite initial reluctance was given as an illustrative example.

The potential impact to laboratories in the developing world was revisited multiple times throughout the day and it was recognized that many laboratories would lack the resources necessary to become certified and maintain their certifications. However, participants also discussed examples of laboratories throughout the developing world that have been certified to other standards. And some of the participants from developing countries at the meeting spoke about their strong interest in an internationally-developed certification scheme so that their best laboratories could achieve appropriate recognition. Flexibility in certification was considered, possibly allowing multiple levels of certification (e.g. bronze, silver, gold).

Need for a harmonized scheme

Already multiple approaches to certification and accreditation are in different stages of development and implementation but, because infectious diseases and the scientific enterprise are global, harmonization will ultimately be necessary. Is it possible to develop a harmonized scheme now? Food safety was highlighted as an undesired example: by not collaborating on the development of a harmonized certification scheme at the outset, that community now has more than 7 or 8 schemes in use.

Those developing a certification scheme should learn from current experiences and challenges with implementation, such as those by the US National Institutes of Health and the Singapore Ministry of Health, but also from examples outside of the biocontainment arena. Existing certification schema should be collected and analyzed to look for areas already aligned and current discrepancies.

An internationally-accepted certification scheme could facilitate international collaborations by providing some level of assurance between collaborating partners. One laboratory representative indicated the concern about collaborations damaging their reputation if something undesired happens at a collaborating laboratory operating under different biorisk standards.

In country approaches for certification should be developed to support implementation of a harmonized scheme. This is particularly relevant to donors; "if we

are building laboratory capacity, then we also need to build the support systems to sustain that capacity." A certification scheme would be a useful platform for education and training, even for laboratories not seeking certification.

Upholding value of the CWA
A recognized certification scheme, supported by accreditation of certifiers, could be important for ensuring that the value of the standard is not diluted over time due to inconsistent certification.

This could be especially important for the biosecurity aspects. Due to its longer history, biosafety is more well-established but the CWA and an associated certification scheme could be a useful vehicle for facilitating appropriate, risk-based implementation of biosecurity.

Scheme ownership
Resources will be needed to maintain a laboratory biorisk certification scheme. The group did not devote much time to discussing who should own a certification scheme. However, the group recognized the importance of this topic but felt that it could be addressed at a later date once the outlines of a certification scheme were developed.

Timing
There was no consensus on how quickly this proposed effort should move forward. Some participants believed that there was a strong need to develop a certification scheme as soon as possible to give interested parties a common basis for certification while others felt that initiating a process to develop a certification scheme now could divert resources from WS 55, negatively impacting its effort to develop a guidance document for the user community.

Process for next steps
The group discussed ways to initiate the development of a certification scheme but did not identify the most appropriate mechanism. Another CEN process was acknowledged as one possible avenue but because of possible German national regulatory implications and the truly international breadth of the assembled stakeholders, the need to explore other options, such as the ISO workshops, was identified.

Agenda

Time		Speaker
09:00	Welcome	
09:15	Stakeholder Introductions	All
09:45	CWA 15793 – Overview and next steps	Stefan Wagener – Public Health Agency of Canada
10:15	Laboratory Certification in Singapore.	Se Thoe Su Yun – Singapore Ministry of

		Health
10:35	ABSA Laboratory Accreditation Task Force	Chris Thompson – American Biological Safety Association
10:55	Towards laboratory biorisk certification in Germany?	Juergen Mertsching – Hannover Medical School
11:15	Coffee	
11:30	Certification – views from a conformity assessment body	Stephen McAdam - DNV
11:50	Management Systems Certification – the role of Accreditation bodies	Rene Gouwens - Dutch Accreditation Council RvA/ Nederlands Normalisatie-instituut
12:20	Lunch	
13:00	Round table discussion regarding the strengths and weaknesses of different approaches	All
14:30	Coffee	
14:50	Identifying a way forward	All
16:30	Adjourn	

Summaries of presentations and associated discussions

Stefan Wagener, Public Health Agency of Canada: CWA 15793 – Overview and next steps

Wagener gave a brief overview of the history and intent of CWA 15793, emphasizing that its primary purpose was to help facilities improve laboratory biosafety and biosecurity. But that it was written to be certifiable as a performance-based management system. CWAs have a three year life span and CWA 15793 will reach the end of its timeframe in 2011. At that point, the initial workshop members can agree to renew it for another three year period, it can be withdrawn , or it can serve as input for further standardization efforts, such as a CEN standard or an ISO standard. Several participants indicated that pursuing a CEN standard would not be the best option because the process strict rules, limiting participation to CEN members and, thus, making the process less international. Because there has been limited experience so far implementing CWA 15793, Wagener voiced the hope that the CWA would be extended for another three years to give more time to users to determine what works and what does not before undertaking any substantive revisions.

Se Thoe Su Yun, Singapore Ministry of Health: Laboratory Certification in Singapore

Su Yun explained their approach to certification as outlined in the slides. The ensuing discussion focused on what works well and what could be improved. She stated the Ministry of Health's desire to build more local capacity for carrying out the certifications and the need to strengthen the biosecurity aspects of the certification. The process was deemed to work well from a user perspective, being relatively unobtrusive to the laboratories. However, one participant spoke about confusion to laboratory workers interviewed during the assessment process, leaving individuals questioning whether their individual competence was being assessed rather than the facility. There was also a

brief discussion about where responsibility lies if there is an incident in a certified laboratory. One participant suggested that it was similar to hospital accreditation in this aspect where certifiers help with improving operations through the certification process but, ultimately responsibility lies with the hospitals themselves.

Chris Thompson, American Biological Safety Association: ABSA Laboratory Accreditation Task Force

Thompson discussed the ABSA effort to develop a voluntary biosafety accreditation process for US containment laboratories. The discussion centered on concerns about liability and conflict of interests. Several participants indicated that this approach would not be accepted internationally due to conflicts of interest from biosafety professionals overseeing an accreditation system impacting the facilities they operate. One participant urged ABSA to look carefully at the bankruptcy of the American Conference of Industrial Hygienists (ACGIH)[5] resulting from an industry lawsuit about standards set by ACGIH and its implications for ABSA. This is the prime reason that CAP and other accreditation systems in the US have set up legally separate entities. It was also noted that ANSI has a working group looking at the development of certification standards based on the NIH standards. There was also some discussion about whether what ABSA is developing is analogous to a formal, standardized peer review process (e.g. ncura.edu).

Juergen Mertsching, Hannover Medical School: Towards Laboratory Biorisk Certification in Germany?

Mertsching explained the efforts underway in Germany to look at how the CWA fits into their legal framework. A formal German subcommittee has done a CWA gap analysis for Germany and concluded that most of the elements of the CWA are already enshrined in German law. But implementing the CWA would positively add biosecurity elements (which are not currently regulated), address toxins, broaden the role of biorisk advisors, and promote ongoing training instead of simply initial training. They also noted the conflict of the CWA with the German legal requirement for certification of worker protection measures.

Stephen McAdam, Det Norske Veritas: Certification – Views from a Conformity Assessment Body

McAdam gave an overview of how typical management systems certification schemes such as ISO 9001 and ISO 14001 operated and argued that a similar approach should be used to build a robust, internationally recognized and trusted certification scheme for CWA 15793. Such a scheme depends on a strong accreditation body or bodies to check that the certification body is working to appropriate standards and using appropriate resources. An accredited certification scheme could benefit from existing the systems, tools and competencies that professional certification and accreditation bodies already have in place to ensure that certification could be offered globally in a uniform manner as possible. McAdam recognized that there was some confusion around the terms certification and accreditation but suggested that, for laboratory biorisk certification, the definitions provided by ISO 17000 should be adopted:

[5] www.acgih.org

Certification - third-party attestation related to products, processes, systems or persons

NOTE Certification of a management system is sometimes also called registration.

NOTE 2 Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.

Accreditation - third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Attestation - issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated

Rene Gouwens, Dutch Accreditation Council RvA / Netherlands Normalisatie instituut: Management Systems Certification – the Role of Accreditation Bodies

Gouwens emphasized the value of accreditation from a government perspective, where accreditation can serve as a mechanism to trust certifiers if the certification scheme is being used by the regulatory sector. He also highlighted the value of dividing the technical standard from the certification scheme since they have different users and evolve over different time frames. Competent ownership of a certification scheme is critical for maintenance and addressing interpretation questions as they arise.